IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCOTT GILMORE,	)	
	)	C.A. No. 20-1085-MN
Plaintiff,	)	
	)	
v.	)	**JURY TRIAL DEMANDED**
	)	
MONSANTO COMPANY,	)	
	)	
Defendant.	)	

DEFENDANT MONSANTO COMPANY'S BRIEF IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF'S COMPLAINT

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INTRODUCTION AND SUMMARY OF THE ARGUMENT

Plaintiff alleges that Monsanto violated the Delaware Consumer Fraud Act ("DCFA") because it sold Roundup®-brand herbicide products without a warning that—contrary to EPA's repeated scientific conclusions and the EPA-approved label—the products' primary active ingredient, glyphosate, is an alleged carcinogen. Plaintiff's complaint should be dismissed in its entirety for four reasons.

Plaintiff has not plausibly alleged facts showing that he has Article III standing. Plaintiff alleges in conclusory fashion that he did not receive the economic benefit of his bargain, but pleads no facts showing that Monsanto "provided h[im] with an economic benefit worth one penny less than what []he paid" for the Roundup® products. *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Liab. Litig.*, 903 F.3d 278, 284 (3d Cir. 2018). Plaintiff also lacks standing to seek injunctive relief because he is "well aware" of the alleged "health risks associated with using" the products and thus cannot plausibly claim he will be deceived again in the future. *Id*. at 292.

Plaintiff's claim is expressly preempted by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which bars any state-law "requirements for labeling or packaging in addition to or different from" its requirements. 7 U.S.C. § 136v(b). FIFRA requires that pesticides be sold without deviation from the EPA-approved label and requires that pesticides not be misbranded by including false or misleading statements. With respect to glyphosate-containing Roundup® products, EPA has repeatedly determined that no cancer warning is warranted. In fact, EPA has concluded that a cancer warning would be *false* and constitute illegal "misbranding." Plaintiff's DCFA claim would thus require a departure from the EPA-approved labeling and a warning that EPA has rejected, and it is therefore preempted by FIFRA.

Plaintiff's claim is preempted under the doctrine of impossibility preemption because there is "clear evidence" that EPA would reject any bid to add a cancer warning to the Roundup® products' labeling. Plaintiff's theory would thus make it impossible for Monsanto "to comply with both state and federal requirements." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 486 (2013).

Plaintiff has not plausibly alleged any facts constituting unfair or deceptive conduct in Delaware as required to proceed under the DCFA. Plaintiff is a Washington resident who purchased the Roundup® products in Oregon. He fails to plausibly allege any relevant fraudulent conduct occurring in or originating from Delaware, and therefore cannot proceed under the DCFA.

FACTUAL BACKGROUND

I. GLYPHOSATE AND THE ROUNDUP® PRODUCTS

Glyphosate is the primary active ingredient in many of Monsanto's Roundup®-brand herbicide products, including the products Plaintiff allegedly bought. D.I. 1 ¶¶ 1, 16, 102. Under FIFRA, all pesticides (including herbicides) sold in the United States must be registered with EPA. 7 U.S.C. § 136a(a). EPA may not register a pesticide unless it finds that it will not cause unreasonable risks to human health or the environment when used as directed in the product labeling. 7 U.S.C. §§ 136a(c)(5)(C), 136(bb). To that end, EPA requires pesticide registrants to provide extensive scientific data, including field trial data on carcinogenicity, toxicity, and other human health risks (7 U.S.C. §§ 136a(c)(1)(F), (c)(2)(A), 136c(a); 40 C.F.R. § 158.500), which EPA substantively analyzes and exercises its expert judgment about before registering any pesticide (40 C.F.R. § 152.112(f)).

As part of the registration process, registrants must submit a complete copy of the labeling to EPA, which must determine that the labeling complies with FIFRA's requirements before registration. 7 U.S.C. § 136a(c)(1)(C), (c)(5)(B). FIFRA prohibits labeling and packaging that is

"misbranded," meaning that pesticide labels must contain adequate instructions for use, include all necessary warnings or cautionary statements, and not be "false or misleading in any particular." 7 U.S.C. § 136(q)(1)(A), (F), (G); *id.* § 136a(c)(5)(B); 40 C.F.R. § 156.10(a)(5)(ii). It is unlawful for any person to distribute or sell the pesticide "if any claims made for it as part of its distribution or sale substantially differ" from its approved labeling. 7 U.S.C. § 136j(a)(1)(B). Registrants are also prohibited from adding a new "health hazard" to the label or changing the formulation of the pesticide without first obtaining EPA's approval. 40 C.F.R. §§ 152.44, 152.46.

Glyphosate has been registered with EPA since 1974. Declaration of Kelly E. Farnan ("Farnan Decl.")[1] Ex. A at 12. In the course of its registration decisions, EPA has repeatedly evaluated the scientific evidence on human health risks of glyphosate and concluded that glyphosate does not pose a risk of cancer in humans, classifying glyphosate in EPA's lowest-risk category since at least 1991. *See id.* Exs. B at 14, A at 13. For example:

Date	EPA Action
1991	EPA classified glyphosate as non-carcinogenic "based on a lack of convincing evidence of carcinogenicity in adequate studies." *Id.* Ex. B at 14.
1993	EPA concluded there was "evidence of non-carcinogenicity in humans." *Id.* Ex. B at viii, 14.
1997	EPA concluded that "[d]ata indicate that glyphosate is a group E carcinogen (evidence of noncarcinogenicity for studies in humans …)." 62 Fed. Reg. 17,723, 17,728 (1997).
2002	EPA found "[n]o evidence of carcinogenicity." 67 Fed. Reg. 60,934, 60,935-43 (2002); *see also* 69 Fed. Reg. 65,081, 65,086 (2004) ("Glyphosate has no carcinogenic potential").

[1] The exhibits to the Farnan Declaration are publicly available on EPA's website and are therefore subject to judicial notice under Federal Rule of Evidence 201 and may be considered by the Court without converting Monsanto's motion into a motion for summary judgment. *See Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1197 (3d Cir. 1993) ("Courts have defined a public record, for purposes of what properly may be considered on a motion to dismiss, to include … letter decisions of government agencies … and published reports of administrative bodies"); *Vanderklok v. United States*, 868 F.3d 189, 205 n.16 (3d Cir. 2017) (taking judicial notice of "information [that] is publicly available on government websites"); *In re Chemed Corp., S'holder Derivative Litig.*, 2019 WL 3215852, at *3 n.6 (D. Del. Feb. 26, 2019) (taking judicial notice on motion to dismiss of "public documents that have been filed with the SEC").

Date	EPA Action
2008	EPA concluded that "glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant." 73 Fed. Reg. 73,586, 73,589 (2008); *see also* 78 Fed. Reg. 25,396, 25,398 (2013).
2015	EPA reevaluated glyphosate and again classified it as "Not Likely to be Carcinogenic to Humans." Farnan Decl. Ex. A at 13, 143-44.
2016 & 2017	EPA concluded that "the available data and weight-of-evidence clearly do not support the descriptors 'carcinogenic to humans,' 'likely to be carcinogenic to humans,' or 'inadequate information to assess carcinogenic potential'" and that the scientific evidence provides "strongest support" for the descriptor "not likely to be carcinogenic to humans." *Id.* Exs. C at 137, 141, A at 143-44; *see id.* Ex. D at 15.
April 2019	EPA concluded that it has "not identif[ied] any human health risks from exposure to and use of glyphosate." *Id.* Ex. E at 35.
August 2019	EPA issued a letter to all registrants of glyphosate-based products stating that, based on its "extensive" review of scientific literature, "including studies submitted to support registration of glyphosate and studies identified by EPA in the open literature as part of a systematic review," glyphosate is "not likely to be carcinogenic to humans" and it would therefore be "false and misleading," and a violation of FIFRA's misbranding prohibition, to include a cancer warning on such products. *Id.* Ex. F at 1.
January 2020	EPA issued its final Interim Registration Review Decision for glyphosate, concluding that "there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." *Id.* Ex. G at 10; *see also* 85 Fed. Reg. 5,957 (2020).

In 2015, the International Agency for Research on Cancer ("IARC") classified glyphosate as "probably carcinogenic." D.I. 1 ¶¶ 30-32. EPA, however, "disagrees with IARC's assessment of glyphosate." Farnan Decl. Ex. F at 1. EPA has explained that its "scientists have performed an independent evaluation of available data since the IARC classification … and concluded that glyphosate is 'not likely to be carcinogenic to humans.'" *Id.* EPA has informed registrants of glyphosate-based products that a cancer warning on those products would be "***false and misleading***" and thus render any product so labeled "***misbranded pursuant to section 2(q)(1)(A) of FIFRA***." *Id.* (emphases added). Consequently, EPA has determined, glyphosate products including such a cancer warning "***do not meet the requirements of FIFRA***." *Id.* (emphasis added).

EPA therefore has stated that it ***would not approve*** any labeling with a cancer warning.[2] *Id.* Ex. F at 2.

II. PLAINTIFF'S ALLEGATIONS

Plaintiff lives in the State of Washington and alleges that he bought Roundup® products "on multiple occasions," including most recently from a Home Depot store in Oregon. D.I. 1 ¶¶ 13, 101-02. He alleges that Monsanto violated the DCFA by marketing and selling Roundup® Lawn & Garden products without disclosing on its product labels, its webpages, or in in-store advertisements the products' "potential to cause cancer." *Id.* ¶ 132; *see also id.* ¶¶ 6-8. Specifically, Plaintiff alleges that Monsanto "leads reasonable consumers into believing Roundup is safe for its intended use" by failing to disclose the alleged risk that the products may cause cancer and identifying on the product label only the risk of "moderate eye irritation," which "gives the false impression eye irritation is the only risk posed by" the products. *Id.* ¶¶ 26, 28-29.

Plaintiff does not allege that he purchased Roundup® products in Delaware or that he has lived in Delaware at any time. He alleges that Monsanto is incorporated in Delaware (but maintains its principal place of business is in Missouri), sells Roundup® products in Delaware, and, without any factual support, that "the material omissions giving rise to Plaintiff's claim arose, in part, in Delaware." *Id.* ¶¶ 11-12, 14, 18; *see also id.* ¶ 101.

Plaintiff acknowledges the repeated regulatory approvals of glyphosate and the Roundup® products but asserts that those approvals were "based on an incomplete and distorted factual record" because Monsanto concealed the risks associated with glyphosate from EPA. *See id.* ¶¶ 77-

[2] EPA reiterated this conclusion in a January 2020 amicus brief filed in the Ninth Circuit, noting that a cancer warning for glyphosate-based products would "warn[] of a cancer risk that, according to EPA's assessment, does not exist" and therefore "constitute[] prohibited misbranding." Brief of U.S. as Amicus Curiae in Supp. of Monsanto at 10, *Monsanto Co. v. Hardeman*, No. 19-16636 (9th Cir.), D.I. 32 ("EPA *Hardeman* Br.").

91. Plaintiff contends that he was unaware that Roundup® products could cause cancer and would not have purchased the products had he known the "truth." *Id.* ¶¶ 104, 136. When he learned the supposed truth, Plaintiff "stopped using the Product." *Id.* ¶ 106. He claims to have suffered "an economic injury" because he was "deprived of the benefit of the bargain because Roundup is worth less than the economic benefit for which [he] bargained due to its potential carcinogenicity" *Id.* ¶¶ 105, 108; *see also id.* ¶ 137. Plaintiff nevertheless claims that he "may purchase Roundup again if he believes Roundup has been reformulated to remove or mitigate its potential risks." *Id.* ¶¶ 107, 138. Plaintiff does not allege that he has suffered any personal injury.

Plaintiff purports to sue on behalf of a nationwide class. *Id.* ¶ 111. He seeks actual damages and an injunction "requiring Defendant to notify consumers of Roundup's potential to cause cancer" or the "existence of a scientific dispute" regarding the same and "[e]njoining Defendant from continuing to engage, use, or employ any unlawful business acts or practices related to the manufacture, promotion, marketing, advertising, distribution, and sale of Roundup." *Id.* ¶¶ 140-142, Prayer for Relief.

LEGAL STANDARD

Courts should grant Rule 12(b)(6) motions when the plaintiff fails to allege the "grounds" of his "entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 678; *Santiago v. Warminster Twp.*, 629 F.3d 121, 128 (3d Cir. 2010). The "heightened pleading requirements [of Rule 9(b)] apply to claims arising under the Delaware Consumer Fraud Act." *Eames v. Nationwide Mut. Ins. Co.*, 2008 WL 4455743, at *13 (D. Del. Sept. 30, 2008), *aff'd*, 346 F. App'x 859 (3d Cir. 2009).

On a motion to dismiss, courts assess Article III standing using the same standard as a motion to dismiss for failure to state a claim. *Finkelman v. Nat'l Football League*, 810 F.3d 187,

194 (3d Cir. 2016). The court assumes the veracity of non-conclusory allegations and determines whether they "plausibly establish the prerequisites of standing." *Id.*

ARGUMENT

I. PLAINTIFF LACKS ARTICLE III STANDING.

To establish standing, a plaintiff must show that he has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Johnson & Johnson*, 903 F.3d at 284 (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016)). Courts must dismiss a putative class action if the named plaintiff lacks standing. *Finkelman*, 810 F.3d at 195. Here, Plaintiff cannot establish an injury in fact.

A. Plaintiff Lacks Standing Because He Does Not Allege an Injury in Fact.

"[B]uyer's remorse, without more, is not a cognizable injury under Article III." *Johnson & Johnson*, 903 F.3d at 281. A plaintiff seeking damages for economic injury thus "must allege facts that would permit a factfinder to value the purported injury at something more than zero dollars without resorting to mere conjecture." *Id.* at 285. When, like here, a plaintiff proceeds on a "benefit of the bargain" theory, the plaintiff must plead facts permitting a determination "that the economic benefit she received in purchasing the [product at issue] was worth less than the economic benefit for which she bargained." *Id.* at 283, 285. Allegations that the product promised was "safe" and the product delivered was "unsafe," and that an unsafe product is "worth less," are *insufficient* to meet this pleading requirement. *Id.* at 289. The complaint need not plead the "exact value" of the economic injury, but it must include "sufficient factual allegations that, if proven true," would establish such an economic injury. *Id.* at 287.

Johnson & Johnson, a case about baby powder, is illustrative of how the Third Circuit applies these principles. The plaintiff there alleged that she suffered economic injury when she

bought baby powder marketed as safe, which she later learned could lead to an increased risk of ovarian cancer. *Id*. at 282. She alleged that by failing to disclose these "significant" risks, the defendant had "been able to sell the product for more than [it] otherwise would have had [it] properly informed consumers about the safety risks." *Id.* at 291 & n.17. She alleged she would not have bought the baby powder had she known of the risk but—like Plaintiff here—alleged no physical injury. *Id*. at 281, 282. The district court concluded that these allegations were insufficient to establish Article III standing, and the Third Circuit affirmed.[3] *Id*. at 281-82, 290.

Johnson & Johnson held that the plaintiff's allegations that the baby powder would have cost less if the defendant had warned of safety risks were insufficient. *Id.* at 287-88. The court rejected the plaintiff's claims that she received an "unsafe" product worth less than the "safe" product for which she bargained for two reasons. *Id*. First, the court refused to presume that the plaintiff would pay less for "unsafe powder" when she had not so pleaded. *Id*. at 289. Second, the plaintiff did not allege that she developed cancer or was at risk of developing cancer, so the court had no choice but to conclude that the product was safe *as to her*. *Id*. at 289-90. Thus, she could not plausibly claim that the product she bought was "unsafe." *Id*. at 290.[4]

This case and *Johnson & Johnson* are analogous in all relevant respects. Plaintiff's only allegation of injury is that "the economic benefit he received in purchasing the [Roundup® products] was worth less than the economic benefit for which he bargained due to [their] potential

[3] Along with the benefit of the bargain theory, the district court considered an "alternative product theory" and a "premium price" theory. *Id.* at 283-84. Here, Plaintiff sues only on a benefit of the bargain theory. *See* D.I. 1 ¶¶ 105, 108, 137.

[4] Similarly, in *Koronthaly v. L'Oreal USA, Inc*., 374 F. App'x 257, 259 (3d Cir. 2010), the plaintiff did not adequately allege injury in fact when she bought lipstick containing lead, stopped using it after learning this fact, and claimed she would not have bought it had she known it contained lead. *Id*. The plaintiff lacked standing because she alleged no adverse health effects. *Id*. at 259. She asserted only "a subjective allegation that ... lead in the lipsticks [was] unacceptable to her, not an injury-in-fact sufficient to confer Article III standing." *Id.*

carcinogenicity." D.I. 1 ¶¶ 105; *see also id.* ¶¶ 108, 137. Like *Johnson & Johnson*, Plaintiff offers no theory of economic harm other than that a "safe" product is worth more than an "unsafe" product. He does not allege that the product he bought was ineffective at killing weeds, or that he has himself suffered any personal injury. He thus offers only a conclusory assertion that he did not get the benefit of his bargain, couched in language substantively identical to what the Third Circuit has held is "inadequate to provide … Article III standing." *See* 903 F.3d at 291.

Plaintiff's allegation that he bargained for a "safe" herbicide and did not get it is precisely the argument the Third Circuit has rejected. *Id.* at 289. Plaintiff alleges no personal injury or risk of developing cancer, and this Court thus must presume that the products are safe *as to him*. *See id.* at 289-90. Because Plaintiff fails to establish a concrete, non-conjectural injury in fact, this Court should dismiss Plaintiff's claim for damages for lack of standing.[5]

B. Plaintiff Lacks Standing for Injunctive Relief Because He Does Not Plausibly Allege that He Will Be Deceived Again.

Even if Plaintiff could establish standing to support his damages claim (which he cannot), Plaintiff lacks standing for injunctive relief. A plaintiff has the burden to establish standing for "*each* type of relief sought." *Id.* at 284 (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009) (emphasis in original)). A plaintiff seeking injunctive relief "must establish that she is likely

[5] Plaintiff may also argue that his case is distinguishable because he did not "consume[] in its entirety" the last product he bought. *Id.* at 281; *see* D.I. 1 ¶ 106. But *Johnson & Johnson* makes clear that this does not salvage his claim. The court distinguished *Cottrell v. Alcon Laboratories*, 874 F.3d 154 (3d Cir. 2017), which held that plaintiffs who alleged they had bought medication packaged in a way that forced them to waste a portion of the product had alleged injury in fact. *Id.* at 167-68. The plaintiffs in *Cottrell* "had standing *only because* they were *unable* to use a portion of the [product] they had purchased, and they alleged an *economic theory* that allowed them to *value* that unused portion." *Johnson & Johnson*, 903 F.3d at 287 (emphases added). That is not what Plaintiff alleges here. Nothing prevents him from using the product he purchased (nor does he limit his putative class to only those individuals who bought Roundup® products they did not use). A "subjective allegation" that the products are "unacceptable to" Plaintiff is inadequate under Third Circuit caselaw. *Koronthaly*, 374 F. App'x at 259.

to suffer future injury from the defendant's conduct." *Johnson & Johnson*, 903 F.3d at 292. The risk of such future harm must be "actual or imminent, not conjectural or hypothetical." *Id*. at 284 (quoting *Spokeo*, 136 S. Ct. at 1548).

Again, *Johnson & Johnson* is fatal to Plaintiff's claim. There, the Third Circuit held that the plaintiff lacked standing to seek an injunction for "corrective advertising" or to enjoin the defendant from "continuing [its] unlawful practices" because she was "well aware of the health risks associated with using" the product at issue. *Id*. at 292. The suggestion that a plaintiff suing for failure to warn of health risks could be deceived by that failure to warn in the future, the Court held, was "unmoored from reality." *Id.*

The injunctive relief Plaintiff seeks here is similar to that sought in *Johnson & Johnson*. *E.g.*, D.I. 1 ¶ 140 (seeking "an order requiring Defendant to notify consumers of Roundup's potential to cause cancer"). And, as in *Johnson & Johnson*, Plaintiff is surely aware of the alleged health risks outlined in his own complaint. Thus, the idea that he is likely to be deceived again is incredible. Indeed, Plaintiff does not even allege that he *will* buy the products again, but only that he "*may* purchase Roundup again *if* he believes it has been reformulated to remove or mitigate its potential risks." *Id.* ¶ 138. (emphases added). This is the very definition of a conjectural or hypothetical injury. Order on Motion to Dismiss at 13-15, D.I. 39, *Hanna v. Walmart, Inc.*, No. 5:20-cv-01075 (C.D. Cal. Nov. 4, 2020). Plaintiff has not plausibly alleged any future injury, let alone one that is actual or imminent.

II. FIFRA EXPRESSLY PREEMPTS PLAINTIFF'S CLAIM.

Even if Plaintiff had Article III standing (and he does not), his claim is preempted by FIFRA, because EPA has repeatedly assessed glyphosate, the Roundup® products, and their labeling, and concluded that a cancer warning is neither required nor permitted by FIFRA.

In a subsection titled "Uniformity," FIFRA includes an express preemption provision prohibiting states from "impos[ing] … any requirements for labeling or packaging in addition to or different from those required under this Act." 7 U.S.C. § 136v(b). Applying this provision, the Supreme Court has held state-law requirements "for labeling or packaging" that impose duties "in addition to or different from those required" under FIFRA are expressly preempted by FIFRA. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 438-44 (2005). Plaintiff's DCFA claim is expressly preempted because it is a state-law "requirement[] for labeling or packaging" that is "in addition to or different from" FIFRA's requirements.

A. Plaintiff's Claim Seeks to Impose a State-Law Labeling Requirement.

Plaintiff's claim seeks to impose a state-law labeling requirement. A state-law duty constitutes a "requirement for labeling or packaging" under FIFRA if it "set[s] a standard for a product's labeling that [defendant's] label is alleged to have violated by containing false statements and inadequate warnings." *Id.* at 446. That describes Plaintiff's claim here. Plaintiff alleges that the warnings on the product labels are inadequate and "give[] the false impression eye irritation is the only risk posed by Roundup, when in fact, glyphosate is known to have links to cancer." D.I. 1 ¶ 29. He alleges that consumers are entitled to a state-law remedy because Monsanto failed to disclose the alleged carcinogenicity of glyphosate, or the "debate" regarding the same, on "Roundup's label itself," or in "other disclosures to consumers" such as product webpages and in in-store advertisements.[6] *Id.* ¶ 109; *see also, e.g.*, *id.* ¶¶ 8, 132. Plaintiff's theory is thus that the

[6] If Plaintiff asserts his claim cannot be preempted to the extent that it relies on such "other disclosures," he is mistaken. "Labeling" includes not just the labels attached to the product itself, but any "written, printed, or graphic matter … accompanying the pesticide [] at any time." 7 U.S.C. § 136(p)(1). "Accompanying" refers not to physical proximity, but to the relationship of the written or graphic matter to the label, and whether it can be "read as providing a supplement to the [] label." *Indian Brand Farms, Inc. v. Novartis Crop Prot., Inc.*, 617 F.3d 207, 218 (3d Cir. 2010).

products' EPA-approved labeling is inadequate for failing to include a cancer warning, and that Monsanto is required by state law to provide a warning not included on that labeling.

Plaintiff seeks to impose this state-law requirement through both an injunction and monetary relief. Both types of relief seek to impose a state-law "requirement for labeling or packaging." *Bates*, 544 U.S. at 447 (damages claims for fraud and failure to warn were "premised on common-law rules that qualify as 'requirements for labeling or packaging.'"); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) (the term "requirement" includes common-law claims, even when the "remedy is limited to damages"); *Farina v. Nokia Inc.*, 625 F.3d 97, 133 (3d Cir. 2010) ("[I]t is the cause of action, and not the specific relief requested, that matters.").[7] Nor does Plaintiff's transparent attempt to avoid preemption by pleading that the injunctive relief he seeks is not a "label change," but rather the disclosure of the alleged risk to consumers through other means, change the analysis. D.I. 1 ¶¶ 66, 140. Plaintiff's claim would impose liability for the omission of a cancer warning premised on the alleged inadequacy of the product labeling and thus seeks to impose a requirement for labeling under state law.

B. Plaintiff's Claim Seeks to Impose a Requirement "In Addition to" and "Different from" FIFRA.

Plaintiff's claim would impose a state-law "requirement for labeling" that is "in addition to or different from" federal requirements imposed under FIFRA. *See* 7 U.S.C. § 136v(b).

Here, Plaintiff claims that the label contains *inadequate* warnings about safety hazards—a key function of EPA-approved labels—and must be supplemented with other warnings.

[7] Although some courts have concluded that claims for damages cannot impose labeling "requirements"—*e.g.*, *Carias v. Monsanto Co.*, 2016 WL 6803780, at *7 (E.D.N.Y. Sept. 30, 2016)—those decisions cannot be reconciled with the Supreme Court's decision in *Bates* or the Third Circuit's decision in *Farina*.

1. Plaintiff's claim is inconsistent with specific federal requirements for the Roundup® products' labeling.

EPA's approval of a pesticide's label has substantive legal effect and compels manufacturers, distributors, and retailers to comply with the label's terms without deviation. *See* 7 U.S.C. § 136j(a); *see also* EPA *Hardeman* Br. at 20-21 ("The EPA approved label is a very formal affair that is the foundation of any FIFRA preemption argument, and that label … establishes 'requirements' sufficient to support a preemption analysis."). Any deviation from the label can lead to criminal and civil penalties. *See* 7 U.S.C. § 136l(a)-(b). Accordingly, any "state-law labeling requirement" that differs from what FIFRA requires cannot "survive preemption." *Bates*, 544 U.S. at 453.[8]

EPA has repeatedly approved labels for the Roundup® products with no cancer warning. *See supra* at 2-4. Those approvals are based on decades of findings that glyphosate poses no cancer risk to humans and that no cancer warning is appropriate. *See id.* Under § 136j(a), use of the EPA-approved label for glyphosate products, containing no cancer warning, is a federal requirement specific to these products that brooks no deviation. EPA underscored that requirement in its August 2019 letter to registrants of glyphosate products notifying them that it would *not* approve such a warning. *See supra* at 2-4; Farnan Decl. Ex. F at 1. A state-law requirement to provide a warning

[8] In *Bates*, it was unclear whether the asserted state-law labeling requirements differed from those established by EPA because the label statements at issue did not concern health or safety, but the product's efficacy. EPA had waived review of efficacy issues under FIFRA under 7 U.S.C. § 136a(c)(5). 544 U.S. at 440, 450. The Court thus recognized the asserted state-law claims might permissibly reinforce the same substantive misbranding requirement included in FIFRA, and remanded for consideration of this issue. *See id.* at 447, 453. Here, in contrast, EPA has addressed the precise labeling question Plaintiff raises, substantively reviewed the scientific evidence, concluded the products do not pose a risk of cancer or other human health risks, and required the use of a label with no cancer warning. *See supra* at 2-4. Because Plaintiff's state-law claim seeks to impose a different and conflicting "state-law labeling requirement," such claim cannot "survive preemption." *Bates*, 544 U.S. at 453.

that deviates from the EPA-approved label in connection with the sale of Roundup® products—a warning that EPA has made clear it would not allow—is surely "in addition to" and "different from" the labeling requirement imposed by EPA under FIFRA.[9]

2. Plaintiff's claim is inconsistent with FIFRA's misbranding provision.

FIFRA makes it "unlawful for any person" to "distribute or sell … any pesticide which is adulterated or misbranded." 7 U.S.C. § 136j. "A pesticide is misbranded if its labeling bears any statement … which is false or misleading in any particular." *Id.* § 136(q)(1)(A). As with the requirement not to deviate from the approved label, FIFRA's requirement not to sell misbranded pesticides is enforceable by criminal or civil penalties. *See id.* § 136l(a)-(b). For decades, EPA has substantively reviewed the scientific evidence of glyphosate safety and has exercised its FIFRA misbranding authority to require the use of a label that does not contain a cancer warning. EPA reiterated its misbranding determination in August 2019 and confirmed that adding a cancer warning to glyphosate products would make those products "misbranded pursuant to section 2(q)(1)(A) of FIFRA [7 U.S.C. § 136(q)(1)(A)]." Farnan Decl. Ex. F at 1.

[9] This conclusion is further confirmed by the Supreme Court's holdings in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), which concerned a preemption provision in the Medical Device Amendments of 1976, 21 U.S.C. § 360k, that (as *Bates* noted) is identical in relevant part to FIFRA's express preemption provision. In *Lohr*, FDA had approved the medical device for sale, but it had never undergone premarket approval for safety and efficacy. Because FDA had established no "requirements" for safety and efficacy, the plaintiff's tort claims were not preempted. *See Lohr*, 518 U.S. at 492-502. In *Riegel*, by contrast, FDA had approved the safety and efficacy of the device at issue, and the manufacturer could make "almost no deviations" without FDA's further approval. 552 U.S. at 319. The Court held that this approval imposed federal "requirements" specific to the device, and any additional or different state-law tort requirements were expressly preempted. *Id.* at 322-23. Here, as in *Riegel*, EPA has established federal "requirements" for the Roundup® products' labeling. And, as in *Riegel*, EPA's approval triggers specific and mandatory federal labeling requirements that preempt any additional or different state-law requirements.

Bates confirms that EPA's misbranding determination expressly preempts Plaintiff's claim. There, the Court explained that "a state-law labeling requirement is not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." 544 U.S. at 447. By contrast, if state law requires a pesticide's label to say "DANGER" where EPA decides it should include "the more subdued 'CAUTION,'" the state-law requirement "would be pre-empted." *Id.* at 453. Here, the difference between the state- and federal-law requirements is not just a matter of degree like "DANGER" and "CAUTION"; the requirements are directly opposed, with Plaintiff alleging that state law requires a cancer warning and federal law prohibiting such a warning. Far from being "fully consistent with FIFRA's misbranding provisions," the state-law requirement Plaintiff alleges here would cause Monsanto to violate FIFRA's misbranding provisions, as EPA has specifically confirmed. *See* Farnan Decl. Ex. F at 1. A registrant cannot be held liable under state law for failing to mislabel its pesticide in violation of FIFRA. Plaintiff's claim is expressly preempted by § 136v(b).

III. PLAINTIFF'S CLAIM IS ALSO BARRED BY IMPOSSIBILITY PREEMPTION.

For two reasons, Plaintiff's claim is also barred under the doctrine of impossibility preemption, which preempts state law "where it is 'impossible for a private party to comply with both state and federal requirements.'"[10] *Bartlett*, 570 U.S. at 473; *Farina*, 625 F.3d at 122.

A. EPA Has Expressly Stated that it Will Not Approve the Very Warning Plaintiff Seeks.

Plaintiff's claim is barred by impossibility preemption because EPA would exercise its lawfully delegated authority to reject any attempt to add a cancer warning to the Roundup®

[10] "[T]he existence of an 'express preemption provision does *not* bar'" or weaken the impossibility preemption doctrine. *Arizona v. United States*, 567 U.S. 387, 406 (2012) (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869-72 (2000)); *Farina*, 625 F.3d at 130.

products' labeling. Federal law preempts state warning and design claims if there is "clear evidence" the federal agency would not have approved the warning purportedly required by state law. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672-78 (2019); *Wyeth v. Levine*, 555 U.S. 555, 568, 571-72 (2009). Clear evidence exists when the regulator (1) was "fully informed" of the "justifications for the warning," and (2) communicated its rejection of that risk through agency action "carrying the force of law." *Albrecht*, 139 S. Ct. at 1678-79. Both prongs of the "clear evidence" test are met here.

First, EPA was "fully informed" about the supposed evidence that glyphosate is carcinogenic. As explained in the background section above, the agency has repeatedly undertaken in-depth scientific reviews of the evidence on glyphosate's safety, and repeatedly concluded that it is safe and non-carcinogenic. *Supra* at 2-4. These determinations were based on extensive review of scientific evidence, including an open literature review, and the most recent determinations came *after* all of the supposed "evidence" of glyphosate's carcinogenicity cited in the complaint. Farnan Decl. Ex. F at 1. In fact, EPA explained in its August 2019 letter that "EPA scientists have performed an independent evaluation of available data," and that it "considered a more extensive dataset than IARC." *Id.* Additionally, EPA's determinations followed a lengthy opportunity for public comment. *Id.* Exs. E at 6-7, G at 4-5. It is thus beyond question that EPA is "fully informed."[11]

Second, EPA's consistent findings that glyphosate poses no cancer risk to humans, and that no cancer warning is warranted, constitutes clear evidence that the agency would not have

[11] Plaintiff alleges that EPA's repeated registrations of glyphosate and approval of Roundup® product labels were "based on an incomplete and distorted factual record, largely due to efforts on the part of Monsanto to conceal glyphosate's risks." D.I. 1 ¶ 77; *see id.* ¶¶ 77-91. But such "fraud-on-EPA" claims are preempted by FIFRA. *See Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1205 (9th Cir. 2002).

approved a request to add a cancer warning. Indeed, EPA's August 2019 letter *expressly* informed registrants that it would not approve such a warning. *Id.* Ex. F at 1. And its January 2020 Interim Registration Review Decision, issued after notice and comment, reiterated that "there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans." *Id.* Ex. G at 10. These documents confirm what has been true for decades: EPA does not believe glyphosate is a carcinogen, views a cancer warning as false and misleading, and "would not approve a change to the [product's] label to include" a cancer warning. *Id.* Ex. F at 1.

B. Plaintiff's Claim Is Barred by Impossibility Preemption Because Monsanto Cannot Independently Add the Warning Plaintiff Seeks.

Separate from the "clear evidence" test, impossibility preemption also bars Plaintiff's state-law claim because Monsanto cannot unilaterally change its products' formulations or add a cancer warning to the label without EPA approval. Impossibility preemption applies when a defendant cannot "independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011); *see also In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150, 162 (3d Cir. 2014) ("[M]anufacturers cannot unilaterally change a generic drug's labeling, and therefore a state-law claim premised on such a manufacturer being obligated to revise its label is preempted."). *Mensing* held that state-law failure-to-warn claims against generic drug makers were barred because federal law requires generic drug labels to be identical to corresponding branded drug labels. 564 U.S. at 615-18. Thus, if the defendants "had independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id.* at 618. Similarly, in *Bartlett*, the plaintiff's design defect claim against a generic drug maker was preempted because it would have required the defendant to "change [the drug's] labeling to provide stronger warnings," and thus "*not* to comply with federal law." *Bartlett*, 570 U.S. at 475.

Just as the drug makers in *Mensing* and *Bartlett* were barred from independently changing their labels, Monsanto cannot provide the warning Plaintiff demands without EPA approval. EPA approval is required for "any modification in the composition, labeling, or packaging of a registered product." 40 C.F.R. § 152.44(a). Minor clerical modifications can be made without prior EPA approval. *See* 40 C.F.R. §§ 152.44(b)(3); 152.16(a), (b). But any cancer warning would have to be in the "precautionary statements" section of the label. *See* 40 C.F.R. § 156.70(a). And a registrant cannot add a new health hazard to the "precautionary statement" of the label without EPA approval. *See* 40 C.F.R. §§ 152.44, 152.46; EPA, Pesticide Registration Notice (PRN) 98-10: Notifications, Non-Notifications and Minor Formulation Amendments (Oct. 22, 1998) at 8-9. Because Monsanto could not add the warning Plaintiff asserts the DCFA requires "without first obtaining the approval of a federal regulatory agency."[12] *Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 9 (1st Cir. 2018), Plaintiff's claim is barred by impossibility preemption.

IV. PLAINTIFF DOES NOT PLAUSIBLY ALLEGE ANY FACTS THAT COULD CONSTITUTE UNFAIR OR DECEPTIVE CONDUCT IN DELAWARE.

Plaintiff—a Washington resident who bought Roundup® products in Oregon—does not plausibly allege any facts constituting unfair or deceptive conduct within Delaware. The DCFA is expressly limited to "practices in the conduct of any trade or commerce *in part or wholly within this State*." Del. Code ann., tit. 6, § 2512 (emphasis added). The Delaware Supreme Court has therefore held that a DCFA complaint must be dismissed if the plaintiff fails to "allege that any of the conduct at issue took place in Delaware." *Wal-Mart Stores, Inc. v. AIG Life Ins. Co.*, 901 A.2d

[12] It is no answer to say that Monsanto could simply stop selling the Roundup® products altogether. The Supreme Court has rejected this type of "stop-selling rationale," which would "render impossibility pre-emption a dead letter and work a revolution in [the] Court's pre-emption case law." *Bartlett*, 570 U.S. 472, 475 (2013); *see also In re Fosamax*, 751 F.3d at 164 ("*Bartlett* categorically rejected [the stop-selling] theory").

106, 117 (Del. 2006); *see also Marshall v. Priceline.com Inc.*, 2006 WL 3175318, at *2 (Del. Super. Ct. Oct. 31, 2006) ("[C]ourts have consistently ruled that the DCFA is only applicable if the fraudulent conduct occurs within Delaware").

A defendant's incorporation or conduct of business in Delaware is insufficient to establish DCFA standing. *E.g.*, *Chudner v. TransUnion Interactive, Inc.*, 2010 WL 11710658, at *1 n.1 (D. Del. Mar. 4, 2010); *Nieves v. All Star Title, Inc.*, 2010 WL 2977966, at *5 (Del. Super. Ct. July 27, 2010) ("[T]he Court must focus on the location of the transaction and the defendant's conduct."). Instead, a plaintiff must allege specific fraudulent conduct between the plaintiff and the defendant within or originating from the state. *See, e.g.*, *Chudner*, 2010 WL 11710658, at *1 n.1 (dismissing Oregon resident's claim because the "internet transaction at issue … ha[d] no connection to Delaware," even though defendant was a Delaware corporation); *Marshall*, 2006 WL 3175318, at *2 n.11 (dismissing non-residents' claims because complaint did "not assert that any specific act between the named Plaintiffs and the Defendant took place in Delaware," even though some class members accessed defendant's website from within state or used it to book in-state hotels). A plaintiff must plead such allegations with particularity. *See Marshall*, 2006 WL 3175318, at *2 n.11; *Eames*, 2008 WL 4455743, at *13 (Rule 9(b) applies to DCFA claims).

Plaintiff's complaint fails to plausibly allege any facts that would link the alleged omissions at issue to conduct by Monsanto in Delaware. As in *Chudner*, 2010 WL 11710658, at *1 n.1, Plaintiff does not claim to be a Delaware resident or that he bought the Roundup® products in Delaware. Indeed, Plaintiff concedes he is a Washington resident, did not reside in Delaware at any relevant time, and purchased the products in Oregon. D.I. 1 ¶¶ 13, 101-02. Plaintiff does not contend that any of the alleged omissions on the product label, Monsanto's webpages, or in in-store advertisements on which *his* claim is based were made in Delaware. As in *Marshall*,

Plaintiff's complaint fails to "assert that any specific act *between the named Plaintiffs and the Defendant* took place in Delaware." 2006 WL 3175318, at *2 n.11 (emphasis added).

Plaintiff tries to avoid this problem with artful pleading, alleging that (1) Roundup® products are, as a general matter, sold in Delaware; (2) Monsanto submits to Delaware's "law and forums with respect to Roundup," presumably through agreements with parties other than Plaintiff; and (3) "the material omissions giving rise to Plaintiff's claim arose, in part, in Delaware." D.I. 1 ¶¶ 11-12, 15, 17-18, 20. But, for the reasons described above, allegations that Roundup® products are sold in Delaware and that the state's law governs certain agreements to which Plaintiff is not a party have no bearing on the allegedly fraudulent conduct *directed to Plaintiff*.

Plaintiff's allegations that the allegedly fraudulent conduct "arose" or "originate[d]," in part, in Delaware (D.I. 1 ¶¶ 12, 18) are conclusory and implausible and therefore must be disregarded. *Santiago*, 629 F.3d at 128, 130. Plaintiff alleges no specific facts from which a reasonable inference could be drawn that Monsanto developed any of the product labels, webpages, or in-store advertisements in Delaware. To the contrary, Plaintiff alleges that Monsanto's "principal place of business [is] in St. Louis, Missouri." D.I. 1 ¶ 14. As in *Marshall*, Plaintiff's only "assertion with respect to specific contact with Delaware is that [Monsanto] is incorporated within the state." 2006 WL 3175318, at *2 n.11; *see* D.I. 1 ¶ 14. That is insufficient to survive a motion to dismiss. *Id.* at *2 n.11.

CONCLUSION

For the foregoing reasons, this Court should dismiss Plaintiff's complaint with prejudice.

/s/ Kelly E. Farnan

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